



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFZ-35
Food and Drug Administration

July 21, 2004

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref: 04-DAL-WL-24

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gary W. Brownd, Division Manager
Lextron Texas LLP
P.O. Box 1697
Hereford, Texas 79045

Dear Mr. Brownd:

An investigator from the US Food and Drug Administration (FDA) conducted an inspection at your veterinary drug retail store located at West Highway 60, Hereford, Texas 79045, on March 2-5, 2004. The investigation confirmed that you dispensed the prescription drug, flunixin meglumine, to [REDACTED] in an extra-label manner contrary to the order of Dr. [REDACTED] a licensed veterinarian.

Extra-label use of approved animal drugs is permitted under section 512(a)(4)(A) of the Federal Food, Drug, and Cosmetic Act (the Act) if the drug is used in compliance with regulations at Title 21 Code of Federal Regulations (21 CFR), Part 530. Because you did not dispense such drugs in conformance with 21 CFR Part 530, the drugs you dispensed were unsafe under section 512(a) of the Act and adulterated under section 501(a)(5) of the Act.

Our investigation revealed that your firm received monthly, faxed prescriptions from Dr. [REDACTED] for [REDACTED] from April 2003 through September 2003. Each prescription included approximately [REDACTED] different drug products for [REDACTED]. Each month, your firm delivered approximately [REDACTED] bottles of flunixin meglumine to [REDACTED]. During a February 12, 2004 visit to [REDACTED] two bottles were found labeled contrary to Dr. [REDACTED] prescription orders.

- One bottle of flunixin meglumine was labeled with a prescription label, which directed 2 ml per head administered intramuscular (IM) with no meat or milk withdrawal. Dr. [REDACTED] prescribed orders for use of the drug indicated 1 mL per

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100 lbs administered intravenous (IV) with a 4 day meat withdrawal and a 72 hour milk withhold.

- A second bottle of Flunixin meglumine did not bear a prescription label. The manufacturer's immediate labeling on the bottle does not describe dosage, frequency, route of administration and duration of therapy.

Your dispensing of flunixin meglumine in these two circumstances deviated from 21 CFR Part 530. Specifically, the animal drug did not bear and was not accompanied by labeling information adequate to assure the safe and proper use of the product. The label did not contain the directions for use specified by the veterinarian such as the dosage, frequency, route of administration, and duration of therapy as required by 21 CFR 530.12(c).

Additionally, because these drug products were dispensed without adequate directions for use, they are misbranded under section 502 (f)(1) of the Act.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office, in writing, within fifteen (15) working days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to Sherrie L. Krolczyk, Recall and Emergency Coordinator, at the above letterhead address.

Sincerely,



Michael A. Chappell
Dallas District Director

MAC:slk